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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,462	05/26/2000	Stephen Fox Heinemann	SALK1590-3	2034
30542	7590	08/23/2004	EXAMINER	
FOLEY & LARDNER			ULM, JOHN D	
P.O. BOX 80278			ART UNIT	
SAN DIEGO, CA 92138-0278			PAPER NUMBER	

1646

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,462

Applicant(s)

HEINEMANN ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are allowed.
- 6) ☒ Claim(s) 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1) Claims 7 and 34 to 44 are pending in the instant application. Claims 7, 34, 39 and 42 have been amended as requested by Applicant in the correspondence filed 17 March of 2004.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 March of 2004 has been entered.

5) Claim 7 is allowable as written. Further, a claim to a "substantially pure nucleic acid encoding the amino acid sequence presented in Figures 9A, 9B and 9C" would also be allowable if submitted, as would claims to a vector and host cell comprising that nucleic acid.

6) Claim 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and if rewritten in independent form.

7) Claim 38 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

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Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 38 can be infringed by a polynucleotide composition that does not infringe claim 34. See M.P.E.P. 608.01(n)III.

8) Claims 34 and 36 to 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record as applied to claims 5, 8, 9 and 11 to 17 in section 6 of the office action mailed 22 October of 2001. As essentially stated therein, the instant specification does not describe a nucleic acid that is encompassed by the instant claims that does not encode the amino acid sequence presented in Figures 9A to 9C of the instant application. The instant claims potentially encompass a very large genus of polynucleotides encoding an equally large genus of proteins, of which the instant specification only provides an adequate written description of one species of protein within the recited genus. One of ordinary skill would hardly consider one species of protein within the recited genus to be a representative number of species. *In re Clarke*, 148 USPQ 665, (CCPA 1966) held that;

“ It appears to be well settled that a single species can rarely, if ever, afford support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions

do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably large number of reductions to practice would probably be necessary."

9) Claims 34 and 36 to 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims encompass a polynucleotide "encoding a beta2 subunit of a neuronal acetylcholine receptor" having other than that single, naturally occurring amino acid sequence presented in Figures 9A to 9C of the instant application. The instant specification, however, does not provide the guidance that would be needed by a artisan to produce a functional neuronal acetylcholine receptor beta2 subunit protein having anything other than the naturally occurring amino acid sequence presented in the instant specification without resorting to a substantial amount of undue experimentation. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance

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with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

In the instant case, the specification does not identify those amino acid residues in the amino acid sequence presented in Figures 9A to 9C of the instant application which are critical to the structural and functional integrity of a neuronal acetylcholine receptor beta2 subunit protein and those residues which are expendable. The instant specification does not identify even a single structurally and functionally related protein in the prior art for which this information is known and could be applied to that sequence by analogy. Whereas the instant claims encompass an extraordinarily large number of non-naturally occurring neuronal acetylcholine receptor beta2 subunit proteins having a substantial number of modifications relative to that single, naturally occurring protein which is described in the instant specification, there is not even a single working example of a modified neuronal acetylcholine receptor beta2 subunit protein. In the complete absence of guidance or working examples an artisan can not make a polynucleotide encoding a functional neuronal acetylcholine receptor beta2 subunit protein whose amino acid sequence differs from the one presented in Figures 9A to 9C by even a single amino acid and predict "by resort to known scientific law" if the modified protein will function as a neuronal acetylcholine receptor beta2 subunit. And if

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the modified protein does not function as a neuronal acetylcholine receptor beta2 subunit, the instant specification does not disclose how to use it.

10) Claims 34 to 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10.1) Claims 34 to 44 are vague and indefinite in reference to the term "beta2" for those reasons of record as applied to claims 5 to 9, 11, 12, 14 to 27 in section 7 of Paper Number 6 and claims 5, 6, 8, 9, 11, 12, 14 to 27, 31 and 32 in section 9.2 of Paper Number 8. Applicant's traversal of this rejection essentially restates those arguments of record that have been previously answered. The argument that the structural and function limitations recited in the claims defines the limitation "beta2" ignores the basis of the rejection. As stated in the original rejection, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "beta2" subunit an artisan can not determine if a compound **which meets all of the other limitations of a claim** would then be **included** or **excluded** from the claimed subject matter **by** the presence of **this limitation**.

10.2) Claims 39 to 41 are vague and indefinite because the limitation "under high stringency conditions" is conditional and no specific, defining set of hybridization conditions is recited in the specification or the claims. Applicant has traversed this rejection on the premise that this term is known in the art. The articles cited by Applicant in support of their position are silent of the state of the art at the time that the

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instant application was filed. Further, these articles show that this term has varied definitions in the art and therefore, in the absence of a specific and defining set of conditions, an artisan has no way of knowing which set of "high stringency conditions" sets the metes and bounds of the instant claims.

10.3) Claims 42 to 44 are vague and indefinite because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an alpha2, alpha3, alpha4, alpha5, beta3 or beta4 receptor subunit, rendering it impossible to determine the metes and bounds of these claims.

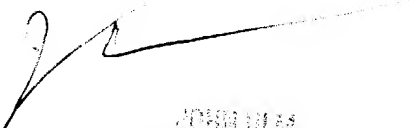
11) Applicant's arguments filed 17 March of 2004 have been fully considered but they are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN HILL
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